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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,524	03/03/2005	Shishan Ji	1547/2	3049

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EXAMINER

GUDIBANDE, SATYANARAYAN R

ART UNIT PAPER NUMBER

1654

DATE MAILED: 12/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/506,524

Applicant(s)

JI ET AL.

Examiner

Satyanarayana R. Gudibande

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date, ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 10, drawn to a conjugate of the formula shown claim 1 wherein TA is an amino acid.

Group II, claim(s) 10, drawn to a conjugate of the formula shown claim 1 wherein TA is a protein.

Group III, claim(s) 10, drawn to a conjugate of the formula shown claim 1 wherein TA is enzymes.

Group IV, claim(s) 10, drawn to a conjugate of the formula shown claim 1 wherein TA is nucleosides.

Group V, claim(s) 10, drawn to a conjugate of the formula shown claim 1 wherein TA is saccharides.

Group VI, claim(s) 10, drawn to a conjugate of the formula shown claim 1 wherein TA is organic acids.

Group VII, claim(s) 10, drawn to a conjugate of the formula shown claim 1 wherein TA is glycosides.

Group VIII, claim(s) 10, drawn to a conjugate of the formula shown claim 1 wherein TA is flavonoids.

Group IX, claim(s) 10, drawn to a conjugate of the formula shown claim 1 wherein TA is quinones.

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Group X, claim(s) 10, drawn to a conjugate of the formula shown claim 1 wherein TA is terpinoids.

Group XI, claim(s) 10, drawn to a conjugate of the formula shown claim 1 wherein TA is phenylpropanoid phenols.

Group XII, claim(s) 10, drawn to a conjugate of the formula shown claim 1 wherein TA is steroids.

Group XIII, claim(s) 10, drawn to a conjugate of the formula shown claim 1 wherein TA is glycosides thereof.

Group XIV, claim(s) 10, drawn to a conjugate of the formula shown claim 1 wherein TA is alkaloids.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. Under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

According to PCT Rule 13.2, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. When Markush groupings is for alternatives of chemical compounds they shall be regarded as being of a similar nature where, A) all the alternatives have a common property or activity and either, B1) a common structure is present, i.e., a significant structural element is shared by all of the alternatives, or B2) in cases where the common structural feature can not be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

In the present instance all the inventions are asserted to be conjugates of formula shown

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in claim 1. However, they do not share a common chemical structure and they are not an art-recognized class of compounds. The test for unity of invention requires both A and either B1 or B2 be satisfied. In the instant case the compound fail to satisfy either B1 or B2. Therefore, no unity of invention exists.

Claims 1-9 and 11-19 link(s) inventions I-XIV. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 1-9 and 11-19. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Election of species

This application contains claims directed to the following patentably distinct species: numerous species of conjugates represented by the formula shown in claim 1. The species are independent or distinct because they represent distinct structures.

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Applicant is required under 35 U.S.C. 121 to elect a **single disclosed species specifying each of the variables shown in the formula shown in claim 1** for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Claim 14 is generic to the following disclosed patentably distinct species: of antitumor agents. The species are independent or distinct because they are chemically distinct compounds. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of the antitumor agent wherein the structure of the antitumor compound is specified clearly by a **structural formula**, because the claim encompasses **derivatives** of the antitumor compounds, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an

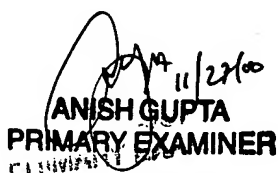
allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana R. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


ANISH GUPTA
PRIMARY EXAMINER

Satyanarayana R. Gudibande, Ph.D.
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